Atty Dkt No. ARC 2865N1 USSN: 09/802,709 **PATENT**

Repeat of the correspondence is being deposited with the United States Postal Service as frst class mail in an envelope addressed to: Assistant Commissioner or Patents, Washington, D.C. 20231 on May 24, 2002

May 24, 2002 Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Lam, et al

Serial No:

09/802,709

Filed:

03/08/2001

For:

METHODS AND DEVICES

FOR PROVIDING PROLONGED DRUG

THERAPY

Group Art Unit: 1614

Examiner: FAY, Z.

Letter

<u>Letter</u>

Honorable Commissioner of Patents and Trademarks Washington, D. C. 20231

Madam:

Applicants received a Notice of Abandonment dated December 19, 2001 regarding the above-identified patent application stating the Applicant's failed to timely file a proper reply to the Office Action mailed on May 29, 2001.

Applicants subsequently received an Office Communication dated May 7, 2002 regarding the above-identified patent application stating that "the amendment filed January 9, 2002 canceling all claims drawn to the elected invention and presenting only claims drawn to a non-elected invention is nonresponsive."

Attached hereto is a copy of the original documents filed in response to the May 29, 2001 Office Action, which were mailed to the U.S.P.T.O. on November 29, 2001, and are as follows:

- Return Receipt Postcard date stamped by the U.S.P.T.O. on January
 2002
- 2. Request for Extension of Time (1 page) (in duplicate)
- 3. Amendment Transmittal Letter (1 page)
- 4. Amendment (4 pages)
- 5. Certificate of Mailing by First Class Mail (1 page)
- Courtesy Copy of Preliminary Amendment filed March 8, 2001 (5 pages)
- 7. Revocation and New Power of Attorney (2 pages)

Applicants did not cancel any further claims in the November 29, 2001 response to the Office Action and Applicants are unaware of any further amendment "filed January 9, 2002" other than the attached response.

Conclusion

Applicants respectfully request that the Notice of Abandonment be withdrawn and await allowance or Office Action responsive to Applicant's November 29, 2001 response.

Please direct any questions to the undersigned at (650) 564-5171.

Respectfully submitted,

Date: May 24, 2002

ву: _

Robert R. Weller Registration No. 46,950

Address:

ALZA Corporation

1900 Charleston Road M-10 Mountain View, CA 94043

Tel: 650-564-5171 Fax: 650-564-2195





JUN 2 4 2002

TECH CENTER 1600/2900

Box	ARC No. #2865N1 - 11
Director of the USPTO Washington D C 20231	Date Mailed November, 29, 2001
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Examiner 2. Fay	Group Art Unit 191614
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Attorney PBS to KMG 15-42-32-128	LES Director of the USPTO

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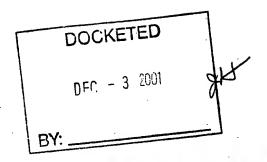
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	ARC No. 12865N1
Box Director of the USPTO Washington, D. C. 20231	Date Mailed: November 29, 2001
Applicant(s) Lam et a1. Serial No. 09/802,709 Examiner: *7. Fay	Filing Date: 03/08/01 Group Art Unit 1614
Documents received in this office: Response to Amendment — L. P. Request for Extension of Time Request for Extension of Time	Tp: dublicate
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'Attorney_PBS_/_KMG	Director of the USPTO

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Applicant(s):	LAM et al.	Examiner	Group Art Unit
Serial No.	Filing Date 03/08/01	Z. Fay	1614
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Note: Each paper must have its own certificate of mailing.

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Re Application Of: La	m et al.		Group Art Unit
		Examiner	1614
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09/802,709	03/08/01 D DEVICES FOR PROVIDING PR	OLONGED DRUG THERAPY	RECEIVED
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Transmitted herewith	inent		
Response to Amenda Request for Extens	sion of Time		
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Paul	& Sunta	Dated: 29 NOV	/ <u>J</u> 001
- france	Signature	certify to 11/29/01 class match Assistant 20231	hat this document and fee is being der with the U.S. Postal Ser with the U.S. Postal Ser in under 37 C.F.R. 1.8 and is addrest Commissioner for Patents, Washington
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CC:

Amendment under 37 C.F.R. §1.111

LAM et al.

Serial No.: 09/802,709

For: METHODS AND DEVICES FOR PROVIDING PROLONGED DRUG THERAPY Filed: March 08, 2001

A petition for a three-month extension of time and the fee therefore accompanies this **Extension of Time** response.

The Rejection Under 35 U.S.C. §103(a)

Claims 1-34 were rejected under 35 U.S.C. §103(a), as obvious over Dong et al. (U.S. Patent No. 5,770,227) and Patrick et al., Biopharmaceuticals & Drug Disposition, 10:165-171 (1989). To the extent the rejection may apply to claims 2 and 58-68, it is respectfully traversed.

Dong et al. relate to a therapeutic composition of progesterone for hormone replacement therapy (column 1, lines 10-16). Dong et al. employ two different tablet cores that are combined to prepare a dosage form for dispensing progesterone to the gastrointestinal tract of a human, (see for example, Example 7 of the specification). The dosage form may further contain an interior surface facing the dual core design and an exterior surface coated on its exterior surface having a semipermeable wall (Example 11). The dosage form may also contain an osmagent (Example 15).

Patrick et al. merely provide a perspective on the absorption of sustained-release methylphenidate formulations compared to immediate release formulations (page 165). This perspective is provided by comparing 3 products: a 10 mg tablet of MPH-IR Ritalin®, a 20 mg tablet of MPH-SR Ritalin®, and a newly formulated 20 mg tablet of MPH-SR from MD Pharmaceuticals (Santa Ana, Ca) (page 166). The authors concluded that the three formulations demonstrated were equivalent in the extent of absorption (page 170).

Applicants respectfully traverse this rejection for a number of reasons. Establishment of a prima facie case of obviousness requires that the cited documents teach or suggest all of the limitations of the rejected claims. In addition, some suggestion or motivation must be provided to modify the documents to reach the claimed invention. Further, a document must be

Amendment under 37 C.F.R. §1.111

LAM et al.

Serial No.: 09/802,709

For: METHODS AND DEVICES FOR PROVIDING PROLONGED DRUG THERAPY

considered as a whole, including those portions of the document that teach away from the claimed invention.

Applicants respectfully submit that all of elements recited in claims 2 and 58-68 are not taught or suggested by Dong et al. and Patrick et al. Moreover, Applicants further submit that one of skill in the art would not be motivated to prepare a dosage form or methods as recited in Applicants' claims.

Dong et al. fail to teach or suggest any dosage form containing a single tablet core coated with a semipermeable membrane. Instead, Dong et al. employ two different tablet cores and combine these cores in a gelatin capsule. Moreover, Dong et al. is unrelated to a method for lessening the incidence of tolerance to methylphenidate to a patient or a method for treating attention deficient disorder in a patient.

Additionally, Dong et al. do not teach or suggest a dosage form that releases drug at a sustained and "increasing" dose as claimed by Applicants. Dong et al. merely provide an "acceptable oral means for administering progesterone at a controlled does over time," (column 1, lines 46-48). Moreover, Dong et al. fail to teach or suggest any dosage form having a single body core. Dong et al. relate only to combining two different tablet cores to prepare a dosage form. And, as pointed out by the Examiner, Dong et al. fail to teach or suggest a CNS acting drug, such as methylphenidate.

The secondary reference, Patrick et al., fails to supply that which is missing from Dong et al. Specifically, Patrick et al. merely provide a perspective on the absorption of sustained-release methylphenidate formulations compared to immediate release formulations. No teaching, suggestion or motivation is provided for the dosage forms and methods as claimed by Applicants.

For the above reasons, Applicants respectfully submit that the invention recited in claims 2 and 58-68 are patentable over Dong et al. in view of Patrick et al. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) are respectfully requested.

Amendment under 37 C.F.R. §1.111

LAM et al.

FOR: METHODS AND DEVICES FOR PROVIDING PROLONGED DRUG THERAPY Serial No.: 09/802,709

In light of the remarks presented herein, it is respectfully submitted that pending claims 2 and 58-68 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representative at the below-listed telephone number if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted, LAM et al., By his Representatives, ALZA Corporation 1900 Charleston Road Mountain View, CA 94043 (650) 564-5000

Paul B. Simboli

Reg. No. 38,616

Attorney for Applicants Direct Dial: (650) 564-7840

PBS/KMG



PATENT Docket No. ARC 2865N1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

1	N THE UNITED	STATESTALL	Group Art Unit:	1614
Applicant(s)	Lam et al.)	Examiner:	Z. Fay
Serial No.:	09/802,709)	•	
Filed:	03/08/2001) Devices for Providir	ng Prolonged Drug Th	ıerapy
For:	Methods and I	Devices 131		

REVOCATION, POWER OF ATTORNEY AND

Director of the USPTO Washington, D.C. 20231

Please revoke any existing Power of Attorney, and appoint the following attorneys to prosecute this application and to transact all business in the U.S. Patent and Trademark Office Dear Sir: in connection therewith.

Owen Bates Pauline A. Clarke Vandana Date John A. Dhuey D. Byron Miller Robert R. Neller Paul B. Simboli	Reg. No. 40,436 Reg. No. 29,783 Reg. No. 38,675 Reg. No. 26,265 Reg. No. 30,661 Reg. No. 46,950 Reg. No. 38,616 Reg. No. 44,394
Samuel E. Webb	Reg. 1

Please send all correspondence to the following address:

Attn: Paul B. Simboli ALZA Corporation 1900 Charleston Road Mountain View, CA 94039-7210

Revocation, Power of Attorney and Certificate Under 37 C.F.R. §3.73(b)

Serial No. 09/802,709

Title: Methods and Devices for Providing Prolonged Drug Therapy Filed: March 8, 2001

ALZA Corporation a corporation organized and existing under and by virtue of the laws of the State of DELAWARE and having an office and place of business at 1900 Charleston Road, Mountain View, CA 94043, certifies that it is the assignee of the entire right, title and interest in the patent application identified above by virtue of an assignment from the inventors, for which a copy thereof is attached. I have reviewed all the documents in the chain of title of the patent application identified above and, to the best of my knowledge and belief, title is in the assignee identified above.

I am empowered to sign this certificate on behalf of the assignee.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true, and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

D. Byron Miller Typed or Printed Name

Assistant Secretary, ALZA Corporation Title

OVIDING PROLONGED DRUG THERAPY Filed: Herewith METHODS AND DEVICES FOR

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PATENT Docket No. ARC2865N1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	LAM et al.) Group Art Unit: Unknown
Serial No.:	Unassigned (Parent: 09/253,317)) Examiner: Unknown)
Filed:	Herewith (Parent: February 19, 1999)))
For:	METHODS AND DEV) YICES FOR PROVIDING PROLONGED DRUC THERAPY

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents **ATTN: Box Patent Application** Washington D.C. 20231

Prior to taking up the above-identified patent application for examination, please amend Sir: the specification as follows:

In the Specification

 \checkmark Please delete paragraph [0001] and insert therefore new paragraph [0001] as follows:

[0001] This application is a continuation of U.S. Application No. 09/253,317, filed February 19, 1999, which is a continuation-in-part of U.S. Application No. 09/070,666, filed April 30, 1998, which is a continuation of U.S. Application No. 08/910,593, filed July 31, 1997, which claims the benefit of U.S. Provisional Application Nos. 60/030,514 and 60/044,121, filed November 12, 1996 and April 22, 1997, respectively.

METHODS AND DEVICES FOR PROVIDING PROLONGED DRUG THERAPY

In the Claims

Please cancel claims 1 and 3-47.

Please add the new claims 48-58:

- A method for lessening the incidence of tolerance to methylphenidate administered to an Attention-Deficit Disorder patient who develops tolerance to methylphenidate, wherein the method comprises administering orally to the patient a dosage form tablet that delivers 100 ng to 500 mg of methylphenidate in a sustained and increasing dose over 16 hours to produce the intended effect.
 - A method for lessening the incidence of tolerance in a patient having Attention-Deficit Disorder, wherein the method comprises administering a pharmaceutically acceptable composition comprising 100 ng to 500 mg of methylphenidate and a pharmaceutically acceptable carrier, that is administered in a sustained and increasing dose for lessening the incidence of tolerance in the patient.
 - A method for treating Attention-Deficit Disorder in a patient, wherein the method comprises administering a pharmaceutically acceptable composition comprising 100 ng to 500 mg of a member selected from the group consisting of amphetamine, dextroamphetamine, methamphetamine, phenylisopropylamine, and pemoline, and a pharmaceutically acceptable carrier, in a sustained and increasing dose for treating Attention-Deficit Disorder in the patient.
 - A method for maintaining the therapeutic effect of methylphenidate in an Attention-Deficit Disorder patient who acquires tolerance to methylphenidate, wherein the method comprises administering orally to the patient a dosage form tablet comprising 100 ng to 500 mg of methylphenidate that delivers the methylphenidate in a controlled and increasing dose over 16 hours to maintain the therapeutic effect in the patient.

METHODS AND DEVICES FOR PROVIDING PROLONGED DRUG THERAPY

- A method for compensating for a decrease in the therapeutic effect to methylphenidate in 52. an Attention-Deficit Disorder patient, wherein the method comprises administering a dosage form tablet comprising 100 ng to 500 mg of methylphenidate to the patient that administers the methylphenidate in a continually-ascending rate over 16 hours to compensate for the decrease in the therapeutic effect.
- A method for treating Attention-Deficit Disorder in a human, wherein the method 53. comprises administering orally to a human having Attention-Deficit Disorder a dosage form that administers a sustained and continuously ascending dose of 100 ng to 500 mg.
- A method of treating Attention-Deficit Disorder in a human wherein the method 54. comprises administering orally to a human having Attention-Deficit Disorder a dosage form that administers a sustained and continuously ascending dose of 5 mg to 75 mg over 12 hours of a drug selected from the group consisting of methylphenidate and its pharmaceutically acceptable salts for treating Attention-Deficit Disorder in the human.
- A method of treating Attention-Deficit Disorder in a human, wherein the method 55. comprises administering orally to a human having Attention-Deficit Disorder a dosage form that administers a sustained and continuously ascending dose of 100 ng to 500 mg over 16 hours of a drug selected from the group consisting of amphetamine, dextroamphetamine, methamphetamine, threomethylphenidate, phenylisopropylamine, and pemoline for treating Attention-Deficit Disorders in the human.
- A method for the management of Attention-Deficit Disorder and Attention-Deficit 56. Hyperactivity disorder in a patient, wherein the method comprises administering orally to the patient a dosage form comprising 100 ng to 500 mg of methylphenidate that is administered in a sustained and continuously ascending dose throughout a school day for the management of Attention-Deficit Disorder and Attention Deficit Hyperactivity Disorder in the patient.

Preliminary Amendment

METHODS AND DEVICES FOR PROVIDING PROLONGED DRUG THERAPY Serial No.: Unassigned

- A dosage form tablet for treating Attention-Deficit Disorder comprising 100 ng to 500 mg of methylphenidate in admixture with a pharmaceutically acceptable carrier that release the methylphenidate in a sustained and increasing dose for treating Attention-deficit Disorder.
 - A dosage form tablet for treating Attention-Deficit Hyperactivity Disorder, comprising 100 ng to 500 mg of a member selected from the group consisting of methylphenidate and its pharmaceutically acceptable salts mixed with a pharmaceutically acceptable carrier that is 58. delivered in a controlled and increasing dose for treating Attention-Deficit Hyperactivity Disorder.

REMARKS

The specification has been amended, i.e., paragraph [0001], to claim priority to parent

Claims 1 and 3-47 have been canceled and claims 48-58 have been added. Upon entry of application, U.S. Application No. 09/253,317. the Preliminary Amendment, claims 2 and 48-58 should be pending in the above-identified

Applicants bring to the Examiner's attention withdrawn U.S. Patent No. 6,034,101 patent application. (courtesy copy enclosed herewith). The claims previously allowed in U.S. Patent No. 6,034,101 (claims 1-11), are the claims now presented by preliminary amendment. This application claims priority to this withdrawn patent, i.e., U.S. Application No. 08/910,593, filed July 31, 1997.

No new matter has been added by these amendments.

Filed: Herewith

METHODS AND DEVICES FOR PROVIDING PROLONGED DRUG THERAPY

The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if there are any questions regarding the above new claims or if prosecution of this application may be assisted thereby.

> Respectfully submitted, LAM et al., By his Representatives, ALZA Corporation 1900 Charleston Road Mountain View, CA 94043 (650) 564-5000

PBS/KMG

Paul B. Simboli Reg. No. 38,616

Attorney for Applicants Direct Dial: (650) 564-7840

Page 1 of 4

LAM et al.

FIREU: METHODS AND DEVICES FOR PROVIDING PROLONGED DRUG THERAPY Serial No.: 09/802,709

PATENT

Docket No. ARC2865N1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant(s):	LAM et al.)	Examiner:	Z. Fay	
Serial No.:	09/802,709) .			
Filed:	08 March 2001))) a rop PRO	VIDING PROL	ONGED DR	U
	- DEVICE	SFORTE			

METHODS AND DEVICES FOR PROVIDING PROLONGED DRUG THERAPY For:

AMENDMENT UNDER 37 C.F.R. § 1.111

Assistant Commissioner for Patents Washington D.C. 20231

Sir:

In response to the Office Action mailed 29 May 2001, Applicants submit the following:

Applicants wish to point out to the Examiner that a preliminary amendment was filed with the above-identified patent application on 08 March 2001. In the preliminary amendment, claims 1 and 3-47 were canceled and claims 58-68 were added. Thus, claims 2 and 58-68 are currently pending in the present application, not claims 1-34 as indicated in the current Office Action (a courtesy copy of the preliminary amendment is submitted herewith).

Applicants will address the rejections as they apply to the present pending claims. Reconsideration and withdrawal of the rejections in light of the preceding amendments and following remarks are respectfully requested.

SPETITION FOR EX	TENSION OF TIME UNDI (Large Entity)	ER 37 CFR 1.136(a)	Docket No. ARC 2865N1
In Re Application Of:			
Serial No. 09/802,709	Filing Date 03/08/01	Examiner Z. Fay	Group Art U 1614
Invention:			
METHODS AND DEVICE	ES FOR PROVIDING PROLONG	GED DRUG THERAPY	
	TO THE ASSISTANT COM	MISSIONER FOR PATENTS:	
Action of May 29, 20 Date The requested extension i	e provisions of 37 CFR 1.136(a) 001 in the above-identified and is as follows (check time period of the control	oplication. desired):	
☐ One month	n 🔲 Two months 🗵 Thre August 29, 2001	ee months	
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class mail under 37 C.F.R. 1.8 and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

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Katrina M. Ghafghaichi

Typed or Printed Name of Person Mailing Correspondence

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PTO/SB/21 (6-98)
Approved for use through 09/30/2000. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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	Application Number	09/802,709
TRANSMITTAL	Filing Date	March 8, 2001
FORM	First Named Inventor	Andrew C. Lam
(to be used for all correspondence after initial filing)	Group Art Unit	1614
	Examiner Name	FAY, Z.
Total Number of Pages in This Submission	Attorney Docket Numbe	ARC 2865N1

ENCLOSURES (check all that apply)		
Fee Transmittal Form	Assignment Papers (for an Application)	After Allowance Communication to Group
Fee Attached	Drawing(s)	Appeal Communication to Board of Appeals and Interferences
Amendment / Response	Licensing-related Papers	Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
After Final	Petition Routing Slip (PTO/SB/69) and Accompanying Petition	Proprietary Information
Affidavits/declaration(s)	Petition to Convert to a Provisional Application	Status Letter
Extension of Time Request	Power of Attorney, Revocation Change of Correspondence Address	Additional Enclosure(s) (please identify below):
Express Abandonment Request	Terminal Disclaimer Small Entity Statement	1- Return Receipt Postcard 2- Letter (2 pages) 3- copies of original documents mailed to the USPTO
Information Disclosure Statement	Request for Refund	on 11/29/2001 (16 pages)
Certified Copy of Priority Document(s)	Remarks	
Response to Missing Parts/ Incomplete Application		
Response to Missing Parts under 37 CFR 1.52 or 1.53		
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT		
Firm or Robert R. Neller; Registratin No.: 46,950; ALZA Corporation		
Signature Robert / Miller		
Date May 24, 2002		

Typed or printed name Maria E. Valenzuela

Signature

Date

Date

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Date

Date

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CERTIFICATE OF MAILING

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